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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Cigna Flip-Flops: Now Says It Will Deny Payment for PC of CP

The College of American Pathologists (CAP) reports that pathologists and labs have received letters from Cigna stating that the insurer now plans to move forward with a new policy that will deny payment of the professional component of clinical pathology (PC of CP). The change will have its greatest impact on hospital-based pathology groups that bill Cigna for professional services they provide to hospital inpatients and outpatients that get clinical lab tests.
Full details, page 8.

In-Office Pathology Lab Slide Mix-Up Leads To Lawsuit For Unnecessary Prostatectomy

Eric Spang, age 48, has filed a medical malpractice lawsuit against The Center for Urologic Care of Berks County (Wyomissing, PA) following a biopsy slide mix-up at the group's in-office histology lab. The error led to a mistaken cancer diagnosis and the unnecessary removal of Spang's prostate. Spang now suffers from urinary incontinence and erectile dysfunction. *Continued on page 10.*

Paige Prostate Gets First FDA Approval For AI-Based Pathology Tool for Cancer

The FDA has cleared the first artificial intelligence-based software product to assist pathologists in diagnosing cancer. The software, called Paige Prostate, is intended to be used for quality assurance by pathologists after their initial review of digitized prostate biopsy slides. After initial review, the Paige Prostate AI software will be run on the digitized images to check if any areas of concern were not identified on the initial pathologist's review.

Some experts believe that this initial FDA clearance will pave the way for as many as 40-50 additional AI-based pathology products to gain FDA approval within the next 12 months. Additional AI product clearances should help speed the adoption of digital pathology.
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Paige Prostate Gets First FDA Approval For AI-Assisted Pathology (*cont'd from page 1*)

In the clinical study submitted by Paige (New York City) to the FDA, 16 pathologists from around the country with varying levels of experience examined 527 slide images of prostate biopsies. One-third of the slides (171 cancer and 356 benign) were from patients with prostate cancer. Each pathologist first assessed the digitized slides and recorded their diagnosis without the assistance of Paige Prostate. The pathologists then reviewed the results from the Paige Prostate software algorithm and recorded their new diagnosis.

Using Paige Prostate was shown to increase pathologists' overall accuracy in correctly diagnosing cancer by 7.3% (from 89.5% to 96.8%). The use of Paige Prostate resulted in a 70% reduction in false negatives and a 24% reduction in false positives, according to the clinical study submitted to the FDA.

Furthermore, Leo Grady, PhD, Chief Executive Officer of Paige, notes that without the Paige AI program the mix of pathologist experience and specialization produced substantial variation in diagnostic accuracy. However, when using Paige Prostate, all pathologist groups benefitted and the gap between those with differing experience and specialization was narrowed significantly, according to Grady.

Grady says that Paige Prostate had its initial pre-submission meeting with the FDA in 2018, was granted breakthrough device status in early 2019, and got final clearance through the FDA's De Novo premarket review pathway in late September. He says Paige will submit additional AI-based products, including Paige Breast Cancer, for FDA clearance in the future. Now that a predicate device has been cleared, subsequent devices of the same type and intended use may go through FDA's 510(k) premarket process and will likely get clearance much quicker, notes Grady.

Up until now, there has been little adoption of digital pathology because, as a standalone product, it provides a limited return on investment. However, the combination of digital pathology with AI software programs brings big clinical benefits from improved accuracy and can also increase pathologist efficiency, according to Grady.

He says that the sales price for Paige Prostate will be dependent on the case and slide volume at each pathology group or lab, as well as the number of users.

More FDA Clearances of AI Pathology Products Expected

Separately, Jochen Lennerz, MD, Medical Director, Center for Integrated Diagnostics at Massachusetts General Hospital, says FDA clearance of Paige Prostate provides a blueprint that other vendors can follow when submitting their AI software products to the FDA. In addition, he believes the FDA recognizes the clinical benefits of AI-assisted pathology and the FDA has an interest in making the review process simpler and quicker. Ideally, Lennerz says that as many as 40-50 additional AI-based pathology products could obtain FDA clearance over the next 12 months.

Ultimately, Lennerz thinks that pathology labs and pathologists will be running two or three AI algorithms from different vendors simultaneously on their slides before and/or after human review.

How Will This New Technology Be Reimbursed?

Now that several digital pathology slide scanners (e.g., Philips IntelliSite in 2017 and Leica Biosystems Aperio in 2019) have been cleared by the FDA as well the first AI software algorithm, Lennerz says the big issue now is reimbursement for these new technologies. "The payers know that AI can help increase the efficiency of the pathologist by up to 20%, so they are likely to use these efficiency gains as a rationale for reduced reimbursement. On the other hand, labs and pathologists will argue that the increased accuracy provided by AI-assisted pathology adds value that should be reimbursed," notes Lennerz.

Spotlight Interview: Digital Pathology Today's Joe Anderson, MD


Joe Anderson, MD

Digital Pathology Today (DPT) is a free podcast that was launched in October 2020 to serve the field of digital pathology. Each week, Joe Anderson, MD, conducts in-depth interviews with scientists, pathologists and lab executives deeply involved with digital pathology. Anderson, a pathologist himself, co-founded *DPT* with Steve Barbee, a digital pathology consultant. Barbee is former President of DigiPath Corp., a digital slide scanner company, and also a former Vice President at BioImagene Inc., a digital pathology firm acquired by Roche in 2010. Below Anderson describes *DPT* and his views on the slow, but accelerating, transition from slide reading by traditional microscope to digital image.

Can you give some more details about *Digital Pathology Today*?
We posted our first episode on October 15, 2020—an interview with Liron Pantanowitz, MD, Director of Anatomic Pathology at University of Michigan Health (Ann Arbor, MI). Our first season included a total of 35 episodes, including interviews with early adopters of digital pathology and artificial intelligence, Sam Terese, CEO of Alverno Laboratories, Mariano de Socarraz, CEO of CorePlus Services, and Cory Roberts, MD, Chairman and President of ProPath. *DPT* is advertiser supported and averages roughly 3,000 to 5,000 viewers per episode—a very respectable number given the specialized content.

Our second season started in mid-September and we're currently posting a new episode every week.

Interestingly, our most popular episode to date was with Jacob Abel, MD, of University of Michigan, who discussed the selection and calibration of computer monitors for digital pathology. This may be because pathologists are most interested in how digital pathology will practically affect how they interpret cases.

Why has the transition to digital pathology occurred so slowly?
When the first slide scanners were introduced in the early 2000s, people wrongly assumed that digital pathology would take off the same way as digitization in radiology. But radiology had a head start because it starts with a native digital image that could more easily be transitioned from film to computer monitor. On the other hand, digital pathology still requires slide preparation and then digitization. The extra step increases turnaround time, staffing, and generally makes things more complicated.

Will AI-assisted pathology speed the adoption of digital pathology?
Historically, the return on investment from digital pathology just hasn't been there and traditional microscopes are not as inefficient as people think. However, applying artificial intelligence to digitized images changes everything.

With reimbursement for anatomic pathology declining, or at best stable, pathology labs and groups must lower costs by increasing pathologist throughput. AI algorithms can help pathologists read more cases per day.

Has any progress been made regarding added reimbursement for digital pathology?
This is something that the Digital Pathology Alliance, which includes representatives from CAP and ASCP, has been working on for the past three years. The extra cost of getting a more accurate cancer diagnosis by using digital pathology and AI should be reimbursed. Possible reimbursement models include new codes for computer-assisted diagnosis. And there is a precedent here with existing code CPT 88361 for computer-assisted breast cancer immunohistochemistry. Another route would be to add new modifiers to CPT 88305-TC when slides are digitized.

What's your current outlook like for digital pathology and AI?
It's not a pie in the sky fantasy. The regulatory requirements have been met and AI is helping to provide an ROI. Digital pathology has nowhere to go but up.

Will digital pathology lead to outsourcing of interpretations to lower-cost foreign pathology labs?
Physician licensing issues make this impractical for clinical diagnostics. Furthermore, the relationship between the pathologist and referring physician is still very important.

The U.S. has the highest per capita number of pathologists, especially subspecialty experts, in the world. Digital pathology is actually more likely to lead to more foreign cases being interpreted by subspecialty experts here in the United States.

What's your advice for pathology groups and labs moving into digital pathology?
Don't assume all staff and personnel will jump on board. Everyone throughout the organization has got to be engaged, including the C-suite, pathologists, IT staff and quality assurance. And be prepared for a long transition to digitization. It doesn't happen overnight and traditional microscope reviews can be run in parallel. Finally, don't underestimate the need for your new digital pathology system to be integrated and compatible with your LIS and billing systems. For more info, see www.digitalpathologytoday.com.

Ibex To Focus On U.S. Market For AI-Assisted Pathology

Ibex Medical Analytics (Tel Aviv, Israel and Boston, MA) has hired Douglas Clark, MD, as its Chief Medical Officer, Americas. Ibex also announced that Joseph Mossel, its co-founder and CEO, is relocating to the United States to lead the company's expansion in North America from its Boston headquarters.

Prior to joining Ibex, Clark was Chief Medical Officer at TriCore Reference Labs (Albuquerque, NM), where he led the transition to digital pathology. Before that, Clark was Chair of the Department of Pathology at the University of New Mexico School of Medicine and was previously Professor of Pathology and Oncology at The Johns Hopkins Medical Institutions.

Ibex develops AI algorithms and digital workflows that help detect and grade cancer in biopsies. The company's AI-powered Galen algorithm is currently being used by CorePlus Services in Puerto Rico (see *LE*, September 2020) and Alverno Clinical Labs in Indiana (see *LE*, August 2021).

Earlier this year, Ibex's Galen platform was granted Breakthrough Device Designation by the FDA, which will help fast-track clinical review and regulatory approval.

Ibex raised $38 million from a Series B financing private equity round in March. Lead investors included Octopus Ventures and 83North, with additional participation from aMoon, Planven Entrepreneur Ventures and Dell Technologies Capital, the corporate venture arm of Dell Technologies. Ibex has now raised a total of $52 million since its inception in 2016.

Khani To Step Down As ACLA President

The American Clinical Laboratory Assn. (Washington, DC) has announced that Julie Khani is resigning as President effective November 26. Khani, who has been ACLA President since January 1, 2017, has accepted a position as Vice President of Government Affairs at Hologic (Marlborough, MA). The ACLA Board of Directors has begun a national search for her successor.

NYSCLA Meeting Highlights: PAMA, Pandemic Response, Shortages & AI

Following cancellation last year due to the pandemic, the New York State Clinical Laboratory Association (NYSCLA) held this year's annual meeting in a well-spaced conference room in Albany, October 6-7. Approximately 125 lab directors, managers, pathologists and vendors were in attendance—down from the average 200+ at pre-pandemic NYSCLA meetings. Key topics discussed included the outlook for the Medicare CLFS under PAMA, the New York clinical lab response to the pandemic, workforce shortages, and the risks and ethical challenges of using artificial intelligence in healthcare. Below are brief summaries of several speaker presentations.

Alan Mertz, Director of Government Relations at **NeoGenomics** (Fort Myers, FL), said the lab industry, led by the American Clinical Laboratory Assn. (ACLA), is lobbying to have Medicare CLFS rates frozen for another year in 2022. This would delay scheduled Medicare rate cuts of up to 15% for most high-volume clinical lab tests, but would not change the second PAMA private-payer data reporting period for labs of January to March 2022.

Another one-year delay would give the lab industry time to try to get legislative changes to PAMA that ensure that all lab providers (independents, hospitals and POLs) are accurately represented through statistical sampling when CMS calculates new CLFS rates for 2023-2025. Other changes sought by ACLA included limiting annual CLFS rate changes to between +5% and -5% per test, increasing the length of time between each data collection period from three years to four years, and excluding Medicaid managed care rates from future surveys.

Mertz noted that ACLA's PAMA lawsuit against HHS/CMS, initially filed in December 2017, has been going on for nearly four years. Most recently, a federal district court dismissed the lawsuit in March, ACLA filed a notice of appeal in May, and hearings are expected to begin later this year.

Separately, Mertz noted that the lab industry has been trying to get clarity from the Department of Justice on the scope of the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) for the past two years. A provision in the EKRA outlaws most traditional volume-based commissions paid to lab sales reps. EKRA was initially intended to target abusive kickback relationships between toxicology labs and addiction treatment centers. It doesn't look like this will be enforced against legitimate labs, but a formal DOJ opinion is needed, according to Mertz.

Finally, Mertz said that ACLA is supporting the VALID Act, which would grandfather in existing laboratory-developed tests (LDTs), but require FDA regulation of new LDTs. This would be preferable to any potential FDA regulations that might be developed under the notice-and-comment rulemaking process. Mertz believes the VALID Act has a chance to pass into law as an attachment to either a drug or medical device user fee reauthorization bill in 2022.

Brian Jackson, MD, Medical Director of Support Services, IT, and Business Development at **ARUP Laboratories** (Salt Lake City, UT), discussed the potential risks and ethical issues associated with using big data and AI in healthcare. Jackson noted how machine learning programs in the past had developed biases as a result of being trained on non-diverse datasets.

Violation of patient privacy is another risk. Jackson noted that Target and other retailers have developed algorithms so sophisticated that they can identify personal medical information based on an individual's purchasing patterns. He cited a study that found that 99.98% of Americans could be correctly re-identified in any de-identified dataset by cross-referencing 15 demographic attributes (Nature, July 23, 2019).

Jackson warned that current FDA regulations of medical AI algorithms are too lax and require very little to achieve clearance. According to a study of 130 medical AI algorithms approved by the FDA between 2015 and 2020: 1) most were based on retrospective data only; 2) 93 out of the 130 devices had only single-site evaluation; and 3) only 17 reported that demographic subgroups were analyzed. [see Wu et al. Nature Medicine 2021;27:576-54]

Jackson urged labs to perform their own validation and quality control studies on new AI applications they deploy, just as they would when adding a new chemistry assay.

On the question of AI algorithms someday replacing pathologist interpretations, Jackson said pathologists may find themselves signing out more cases per day, but "I don't see pathologists being out of work any time in the near future."

James M Crawford, MD, PhD, Senior Vice President of Laboratory Services at **Northwell Health**, noted that Northwell Health Laboratories (system-wide, inclusive of hospital lab-based and Core Lab-based testing, but not including rapid tests performed at Urgent Care Centers) is in the range of 5,000 to 8,000 Covid-19 PCR tests per day. Current positivity rates are hovering between 3% to 4%, according to Crawford.

Positivity rates had averaged more than 70% at Northwell Health at the peak of the pandemic in the New York City area in early April 2020. "We've probably never seen that high of a percentage positivity rate for any other pathogen," noted Crawford.

He said that serological tests ordered by physicians and resulted by Northwell Health Laboratories are currently averaging about 90% positive for antibody tests for "Ig-S" (presumably a reflection of vaccination-related testing) and about 40% for antibody tests for "Ig-N" (presumably tests ordered to see whether a patient had recovered from natural infection). Crawford noted that this testing is from a population in which physicians wanted to know the test results and cannot be viewed as a "serosurvey" of the general population.

Crawford believes the New York City region will continue to see a steady rate of Covid-19 positivity, but that societal function and healthcare delivery will be relatively sturdy through the coming winter months. "Covid-19 will be with us for the foreseeable future. The key is staying committed to our careful ways in co-existence with Covid-19."

Carlos Cordon-Cardo, MD, PhD, Chairman, Department of Pathology, Molecular and Cell Based Medicine at **Mount Sinai Health System** (MSHS-New York City), described Mount Sinai's transition to digital pathology. The timeline included the initial purchase order for Philips IntelliSite Pathology Solution in June 2019, integration of Philips-Sunquest and the MSHS LIS barcode system in late 2019, and going live for clinical diagnostics in early 2020. Labcorp, which acquired the MSHS clinical lab outreach business in 2017, helped with the digital pathology implementation. Cordon-Cardo says that MSHS pathologists are now using a combination of traditional microscope and digital pathology to interpret cases.

"Staffing has become the number one thing on everybody's mind," noted **NYSCLA** President **Eloise Aita, PhD**. She noted that approximately 50% of lab workforce is over the age of 55. Last year, the number of new NYS licensed clinical laboratory technologists fell by 17% to 304, while the number of new clinical lab technicians fell by 8% to 73. Challenges to attracting new workers include poor visibility of the specific occupations in the laboratory and limited job advancement opportunities, according to Aita. "The pandemic has shone a light on the importance of our industry, let's take advantage of that."

Spotlight Interview With Avalon Healthcare's CMO Rahul Singal, MD

Rahul Singal, MD

Blue Cross and Blue Shield of North Carolina (Blue Cross NC) announced recently that it has generated $112 million in cost savings last year by working with the lab benefit manager Avalon Healthcare Solutions (Tampa, FL). Blue Cross NC provides health insurance to 4.2 million members, including approximately 1.1 million on behalf of other Blue Plans. Avalon, which was founded in 2013, is owned by BlueCross BlueShield of South Carolina and several private investors including Francisco Partners and Echo Health Ventures. *Laboratory Economics* recently spoke with Avalon Chief Medical Officer Rahul Singal, MD, about how the company helped drive those savings.

Did the $112 million in lab savings for Blue Cross NC include any reimbursement rate reductions?
No. The Avalon program drives appropriate utilization of lab testing. Most of the savings came from increased appropriate utilization. For example, many doctors will check the box on a lab panel, such as for thyroid. The panel might contain five to seven thyroid tests – TSH is one of them. TSH is the appropriate test for screening for initial diagnosis, and the others are more for follow-up or management of disease, and so they should not be ordered. If a doctor did check thyroid panel and it isn't clinically appropriate, we would render a finding that the TSH was appropriate, but the others were not, so the lab claim would get a partial approval. We have consistently seen that we save 8% to 10% of laboratory spend. We are not incentivized to deny tests.

Isn't the lab being penalized by what the physician orders?
We feel it's a shared responsibility between the laboratory and the physician. Labs need to educate physicians and provide separate boxes for individual tests, not just panels. Avalon helps laboratories review, for example, the top 20 CPT codes that are ordered and do an educational e-mail communication with the referring physician about the appropriate documentation and coding for these tests based on evidence-based medicine.

How do you help steer more lab tests to in-network laboratories?
Two ways. One, as part of rolling out a lab benefit program, we educate providers about why it's important to use in-network lab providers, and then we send periodic reminders. Physicians may know they should use in-network labs, but sometimes they forget. Second, because we now have a system to improve appropriate utilization, the health plan frequently expands its laboratory network. For Blue Cross North Carolina, we also managed the lab network.

Aren't networks actually shrinking?
That has not been our experience. We manage lab benefits for about 20 health plans, and the number of in-network labs has increased in all of them. That's how we have been able to get 99% of the tests done in-network in North Carolina. This compared to 86% before Blue Cross NC signed on with Avalon in 2017.

Roughly how many labs are in-network providers for Blue Cross North Carolina?
Our total network is about 150 labs – that's primarily independent labs and genetic labs. Hospital labs are still contracting directly with Blue Cross NC.

Do you manage networks for other health plans?
Yes, for about one-third of our clients. We have over 20 health plans under contract now; 10 to 12 are live, the rest will go live within the next nine months. Once they are all live, we will cover about 26 million lives. There are a few other laboratory benefit managers, but they are focused primarily on genetic testing. We have a genetic testing component, but we're really the

only technology company that addresses the 90% of the lab spend, which is routine testing.

One of the exciting things we're working on now is working with our laboratory providers to create Lab Insights that will digitize lab values and provide insights to help deliver the right care by the doctors. This initially will focus on conditions like chronic kidney disease, diabetes and cancer. We work with labs to find chronic kidney disease months before it would normally be diagnosed.

What are some other examples of how Avalon helps reduce unnecessary lab test orders?
PSA used to be recommended as a screening test for all men over the age of 50. Now, we have a system to ensure that tests are not necessarily being paid if they are inappropriate. We are able to identify patterns of inappropriate usage prior to our program rolling-out as we analyze historical claims data. This gives us time to educate lab providers and ordering physicians in advance of going live.

What are some other insurance plans that Avalon provides lab benefit management to?
We have about 11 Blue Cross Blue Shield health plans and a variety of other plans across the country, not just commercial but also Medicare and Medicaid membership.

What's the cost difference between using an in-network lab vs. an out-of-network lab?
From a member perspective, if a lab is out of network, the member could have more liability, and they could be balance billed. The difference for the member could be substantial. If an out-of-network lab charges $100 for a test and the health plan does not have a contract with the lab, the plan might only pay $20 and the member could be charged the difference.

Which types of tests are most frequently sent to an out-of-network lab?
Generally various genetic tests. We have comprehensive, evidence-based genetic testing policies, including cancer. The health plan adapts and adopts the policies – and then those health plan policies are on the plans' websites. Our role is to enforce the health plan's adopted policies.

Do you advise health plans on development of policies?
Yes, Avalon has an external, independent clinical advisory board of leading pathologists from academic medical centers – that is public information listed on our website. We have about 150 laboratory policies. The health plans may make modifications to the policies, and then they formally adopt them as part of their medical management committee.

Cigna Flip-Flops: Now Says It Will Deny Payment, (*cont'd from page 1*)

Cigna had initially announced plans to stop paying for the PC of CP effective July 11 (see *LE*, May 2021). Following opposition from CAP and pathologists from around the country, Cigna then announced it would table this planned policy (see *LE*, June 2021).

However, Cigna has once again reversed course and now says it will stop paying for the PC of CP effective beginning in late October through November. Cigna says that its updated PC of CP policy is in alignment with the Medicare National Physician Fee Schedule, which does not recognize the existence of a professional component for clinical lab test codes.

Cigna's updated policy will take effect for claims processed after the following dates:

Illinois:	November 1, 2022
California, Minnesota, and Nevada:	November 11, 2021
Delaware, Massachusetts, Maine, North Carolina, New Hampshire, Puerto Rico, Rhode Island, Tennessee, Virginia, Vermont, and Washington:	November 26, 2021
Arkansas, Colorado, Kentucky, Ohio, and Texas:	December 26,2021
All other states:	October 27, 2021

Source: Vachette Pathology

Tips For Negotiating Your Lab's Next Reference Testing Contract

Reference (aka send-out) testing expenses average between 5% and 10% of the overall budget at most hospital laboratory departments. "Everybody thinks they are getting a good deal, but most have not wrung out the lowest prices available from their reference lab," notes Steve Mattice, President of the hospital lab consulting firm J.A. Mattice & Associates (Portland, OR). Below we highlight some of Mattice's key tips and observations.

What's the "hot list" in terms of send-out tests?
This is the list of 10 to 100 higher-volume send-out tests that the big reference labs (ARUP, Labcorp, Mayo and Quest Diagnostics) will discount the most in order to win a contract. But it's a diversion because they offset their lower prices on the recognizable tests with much higher prices on lower-volume send-out tests. Each of the major reference labs is most focused on the overall profitability of their reference testing contracts.

How can hospitals negotiate for the best overall reference testing contract?
The key is knowing the lowest price that the major reference labs are willing to provide for each specific send-out test. We have helped negotiate more than 100 reference testing contracts over the past 30 years and have maintained a database of the lowest prices we have found for send-out tests from the four largest reference labs. Every time we find a lower price for the same test code, we keep track of it, and it becomes our new standard price for negotiations. When negotiating a new send-out testing contract, we will typically analyze the total annual costs for all send-out tests at a hospital client.

What kind of pricing variation is there?
There is a wide variation (see table). For example, we have found that some hospitals pay their reference lab as little as $9 for Lyme Disease Antibody tests (CPT 86618), while others pay as high as $101. It's not like shopping at the supermarket where you can easily compare prices. In reference testing, like most of healthcare, nobody knows what the other guy is charging.

What kind of savings are you typically able to achieve?
Historically, we have averaged in the range of 23% to 27% savings for each new three-year reference testing contract. However, over the past year, labs have begun to experience inflationary pressure on wages, reagents, paper supplies, courier services, etc. As a result, we've started to see the big reference labs draw a harder line on pricing.

Have there been any new entrants in reference testing to challenge the "big four?"
There are a handful of large health systems and academic medical centers competing on a regional basis and Sonic Reference Laboratory has been making some inroads into the market over the past few years.

Pricing Comparison for Common Send-Out Tests

Test	CPT Code	Low Price	Mid Price	High Price
Actin Antibody	83516	$5	$10	$19
BK Virus Quantitation, DNA	87799	68	82	169
CA 15-3	86300	9	12	21
Cystic Fibrosis Screen	81220	62	80	95
HIV Viral Load	87536	38	57	199
JAK2 Gene Analysis	81270	85	115	299
Lead (Blood)	83655	4	5	8
Lyme Disease Antibody	86618	9	74	101
Methylmalonic Acid (MMA) Test	83921	13	21	29
Testosterone Free & Total LC/MS	84402/84403	24	46	62
Vitamin D 25 Hydroxy	82306	11	23	28

Source: J.A. Mattice & Associates

In-Office Pathology Lab Slide Mix Up Leads To Lawsuit (*cont'd from page 1*)

The lawsuit, filed by Freiwald Law (Philadelphia, PA) on behalf of Spang in May 2021, is seeking an unspecified amount of compensatory and punitive damages. Others named in the lawsuit include Spang's urologist Shawn White, MD; Tower Health, a hospital system contracted to provide histology technician staffing to the in-office pathology lab at The Center for Urologic Care; and the lab's medical director and pathologist Supriya Kuruvilla, MD.

According to the lawsuit, Spang underwent a routine prostate serum antigen (PSA) blood test in September 2020. The result was reported as slightly elevated. A second PSA test performed in November 2020 again showed slightly elevated PSA levels, although lower than the initial test.

In early January 2021, Spang underwent a prostate biopsy, which was performed by Dr. White, who is part owner of The Center for Urologic Care.

The biopsy slides were prepared at the in-office pathology lab at The Center for Urologic Care. Dr. Kuruvilla interpreted Spang's biopsy samples and reported that six of the 12 samples were positive.

In late February 2021, Dr. White performed a radical prostatectomy on Spang. The removed prostate was sent to the pathology lab at Tower Health's Reading Hospital for analysis, which showed no evidence of cancer. Additional slides were prepared and read by more pathologists who confirmed that Spang did not have cancer.

In early March 2021, Dr. White informed Spang that all the samples from his removed prostate tested negative and he did not have cancer.

According to the lawsuit, Dr. White explained to Spang that during the initial prostate biopsy procedure in early January 2021, he had put his biopsy material in a container with Spang's name on it. However, the slides created at the in-office histology lab from Spang's biopsy samples were not individually labeled. The slides were not read until four days later, at which time there were specimens from several patients on the table. This resulted in Spang's slides getting mixed up with another patient who did have prostate cancer.

The defendants filed preliminary objections (the Pennsylvania version of a motion to dismiss) arguing that (a) the physician group and surgery center could not be held directly liable and (b) that plaintiffs were not entitled to punitive damages. The Court overruled both preliminary objections, allowing plaintiffs to proceed. Defendants must file an answer to the lawsuit by October 27, 2021.

Since the alleged mistake, The Center for Urologic Care has switched the management and staffing of its in-office pathology lab from Tower Health to Penn State Health.

Wrong-Patient Prostate Cancer Surgery Cost Iowa Clinic $12 Million

In a separate, but similar case, a Polk County Iowa jury awarded $12.25 million in April 2019 to a man who had his prostate removed, then later learned he didn't have cancer. An Iowa Clinic pathologist mixed up the non-cancerous slides of Rickie Lee Huitt, then age 67, with those of a man who did have prostate cancer.

According to court records, the pathologist said "there were two patients that day that had prostate biopsies" and a "scanner glitch" got Huitt's and another patient's mixed up.

Based on the inaccurate diagnosis, Huitt was told that if he didn't have his prostate removed, he had no more than five years left to live.

Huitt's law firm had asked the jury for an award of $15 million. The Iowa Clinic admitted a mistake had been made but recommended that jurors award only $750,000.

CDx Diagnostics Leads In Digital Pathology

CDx Diagnostics (Suffern, NY), which specializes in oral, esophageal, and laryngeal cancer testing, is by far the biggest digital pathology lab as measured by volume of Part B claims for CPT 88361. CDx was paid for 55,082 Part B tests for CPT 88361 (including combined global, TC-only and PC-only claims) in 2019, according to provider utilization and payment data from CMS.

CPT 88361 is used to bill Medicare for digital quantification of HER2, estrogen receptor (ER), progesterone receptor (PR) and Ki-67 for breast cancer. This code can also be used for digital analysis of other cancers, including oral and esophageal cancers.

NeoGenomics has four labs (California, Florida, Michigan and Texas) in the top 25 with a combined total volume of 19,950 Part B allowed tests for CPT 88361 in 2019.

Sonic Healthcare USA has two lab locations (New York and Texas) that performed CPT 88361 with a combined volume of 6,760 allowed Part B tests for CPT 88361.

Overall, Medicare Part B allowed volume for CPT 88361 totaled 191,205 tests in 2019, down 10% from 212,003 tests in 2018.

Top 25 Labs In Digital Pathology By Medicare Volume of CPT 88361 In 2019

Laboratory/Pathologist Name	*Location*	*Total Allowed Part B Tests*	*Average Part B Allowed Amount*	*Total Part B Allowed Payments*
CDx Diagnostics	Suffern, NY	55,082	$146.26	$8,056,293
NeoGenomics Laboratories	Aliso Viejo, CA	14,612	82.73	1,208,826
Sonic Healthcare/CBLPath	Rye Brook, NY	5,740	153.31	879,999
NeoGenomics Laboratories	Fort Myers, FL	3,423	82.36	281,913
American Specialty Laboratory	Chatsworth, CA	1,895	140.93	267,062
NeoGenomics Laboratories	W. Bloomfield, MI	1,378	47.03	64,809
Quest/AmeriPath Florida	Fort Myers, FL	1,345	72.78	97,889
Quest/AmeriPath Florida	Orlando, FL	1,219	95.34	116,219
Terence Cudahy, MD/Quest/AmeriPath	Indianapolis, IN	1,183	45.34	53,637
Sonic Healthcare/Clinical Pathology Labs	Austin, TX	1,020	118.21	120,574
Inform Diagnostics	Irving, TX	1,020	129.08	131,662
Jamie Donnelly, MD/Analytical Pathology Services	Saint Louis, MO	987	45.25	44,662
Cytometry Specialists, Inc.	Alpharetta, GA	982	87.18	85,611
William Ballance, MD/Greenville Pathology	Greenville, NC	739	118.76	87,764
Thousand Oaks Pathology Associates	Thousand Oaks, CA	738	141.54	104,457
Delta Pathology Group	Shreveport, LA	725	74.39	53,933
Labcorp/Accupath Diagnostic Labs	Brentwood, TN	719	72.07	51,818
Gregory Wellman, MD/Delta Pathology group	Shreveport, LA	662	45.72	30,267
Quest/AmeriPath Indianapolis	Indianapolis, IN	647	73.49	47,548
BioReference Laboratories	Elmwood Park, NJ	627	82.91	51,985
Ningxing Chen, DO/Southeastern Pathology Associates	Brunswick, GA	622	45.58	28,351
NeoGenomics Laboratories	Houston, TX	537	47.41	25,459
Petroglyph Pathology Services	Rio Rancho, NM	536	96.38	51,660
Kirstin Galan, MD/Ascension Medical Group	Wichita, KS	506	62.00	31,372
Paul Guerry, MD/Professional Pathology Services	Columbia, SC	488	45.30	22,106
Total, Top 25 Labs & Pathologists		97,432	123.12	11,995,875
Grand Total, All Labs & Pathologists		191,205	$90.26	$17,258,250

Source: 2019 Medicare Part B Carrier Utilization & Payment Data

Lab Stocks Up 8% Year To Date

Twenty-three lab stocks have risen by an unweighted average of 8% year to date through October 15. In comparison, the S&P 500 Index is up 19% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 171%; Psychemedics, up 64%; and Myriad Genetics, up 61%. Labcorp is up 33%, Quest Diagnostics, +20%, and Sonic Healthcare, +22%.

Company (ticker)	Stock Price 10/15/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value ($ mill)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
Labcorp (LH)	$271.60	$203.55	33%	$30,830	1.9	6.4
Quest Diagnostics (DGX)	142.50	119.17	20%	21,240	1.9	6.1
Sonic Healthcare (SHL.AX)*	39.11	32.15	22%	21,130	2.4	8.3
Exact Sciences (EXAS)	98.96	132.49	-25%	17,140	10.0	NA
Natera (NTRA)	110.77	99.52	11%	10,280	20.4	NA
Guardant Health (GH)	101.60	128.88	-21%	10,060	31.1	NA
Invitae (NVTA)	27.50	41.81	-34%	5,860	15.1	NA
NeoGenomics (NEO)	43.38	53.84	-19%	5,070	10.4	47.2
CareDx (CDNA)	71.00	72.45	-2%	3,010	11.9	NA
Opko Health (OPK)	3.72	3.95	-6%	2,740	1.4	14.4
Veracyte (VCYT)	45.16	48.94	-8%	2,630	16.7	NA
Myriad Genetics (MYGN)	31.74	19.77	61%	2,470	4.4	NA
Fulgent Genetics (FLGT)	78.02	52.10	50%	2,110	2.3	3.2
Castle Biosciences (CSTL)	63.58	67.15	-5%	1,370	17.6	NA
DermTech Inc. (DMTK)	31.28	32.44	-4%	658	72.1	NA
Progenity (PROG)	2.14	5.31	-60%	377	5.0	NA
Aspira Women's Hlth (AWH)	3.14	6.71	-53%	288	48.2	NA
Biodesix (BDSX)	7.50	20.16	-37%	177	2.3	NA
Enzo Biochem (ENZ)	3.78	2.52	50%	165	1.4	20.4
Exagen (XGN)	12.63	13.20	-4%	116	2.5	NA
Interpace Biosciences (IDXG)	8.50	3.14	171%	88	2.3	NA
Psychemedics (PMD)	8.36	5.09	64%	52	2.3	35.1
Biocept (BIOC)	3.86	4.44	-13%	50	0.9	NA
Unweighted Averages			8%	$137,911	12.4	17.6

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from company reports and Capital IQ

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